

## REMARKS

### Status of Application

Applicants respectfully request the entry of the amendments to Claims 26, 30 – 31, 40 – 42, 44 – 45 and 51 and the cancellation of claims 29, 33, 35 – 39 and 48 – 50.

Support for the amendment to claims 26, 30 and 45 is found, for example, at paragraphs 0025-0029 of the published specification, and in the Figures. Support for the amendment to claim 31 is found, for example, at paragraphs 0028-0029 of the published specification, and in the Figures. The remaining amendments merely change dependencies and/or improve clarity. Applicants respectfully submit that the amendments to this pending claim do not introduce any new matter.

Claims 26, 28, 30 – 32, 40 – 45, 47 and 51 remain pending.

### **Rejection under 35 U.S.C. § 112**

Claims 26, 28 – 33, 35 – 45 and 47 – 51 were rejected under 35 U.S.C. § 112 as allegedly failing to comply with the written description requirement. It was contended the claims contain subject matter which was not described in the specification in a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention. It was further alleged that support for the claimed channel relationship of claims 26, 33 and 45 was absent.

Claims 26 and 45 have been amended to better define the claimed invention and relate to support in the specification. The principle of law governing 35 U.S.C. § 112, first paragraph is that the Examiner has the initial burden of presenting evidence or reasoning why one skilled in the art would not recognize in the disclosure a description of the invention defined by the claims *Ex Parte Bass*, BAPI, February 16 2010, citing *In re Wertheim*, 541 F2d. 257, 263 (CCPA 1976). As further explained by the Board in *Bass*:

In order to satisfy the written description requirement, the disclosure as filed does not have to provide *in haec verba* support for the claimed subject matter at issue....A disclosure provides adequate written description if it conveys with reasonable clarity to those skilled in the art that the inventor was in possession of the invention.

Id.

Applying this standard, no reasoning as been presented to support the rejection, which is instead framed as a conclusion. Moreover, since the drawings form a part of the original disclosure, Applicants contend that a deficiency (if any) in the verbal portion of the written description is more than compensated by the drawing. Indeed, Applicants contend the drawing alone is sufficient support for the claims as amended. As now amended, there is ample support for the invention described by the claims, including the structural and functional relationships of the fluid and gas channels to one another.

#### **Rejection under 35 U.S.C. § 102(b)**

Claims 26, 29-33, 36-41, 44-46 and 48-51 were rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by Platz et al., U.S. Patent No. 6,051,256 (hereinafter "Platz").

Applicants respectfully submit that amended claims 26, 28, 30 – 32, 40 – 45, 47 and 51 are patentable under 35 U.S.C. § 102(b) over Platz. Pursuant to 35 U.S.C. § 102, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987), M.P.E.P. § 2131. The identical invention must be shown in as complete detail as contained in...the claims." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989). "The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required." *In re Bond*, 910 F.2d 831 (Fed. Cir. 1990), MPEP § 2131.

The present invention is directed to a novel spray drying system for forming a pharmaceutical formulation that includes an atomizer comprising a first liquid flow channel wherein said first liquid flow channel comprises a constriction having a diameter less than 0.51 mm (0.020 in) for spreading a liquid into a thin film in the channel, the atomizer further comprising first and second gas flow channels for an atomizing gas flow, wherein said first liquid flow channel is intermediate to the first and second gas flow channels, said first and second gas flow channels being positioned so that the atomizing gas impinges the liquid thin film to produce droplets, a drying chamber to dry the droplets to form particles, and a collector to collect the particles.

Platz does not teach, disclose or suggest at least the feature of a first liquid flow channel intermediate to the first and second gas flow channels. Nor does Platz teach, disclose or suggest, with reference to amended claims 30 and 45 that the channels are annular and concentric. Indeed Fig. 3 of Platz (the only Fig. to depict the atomizer *per se*, shows a circular liquid feed channel, surrounded by a fluid gas channel.

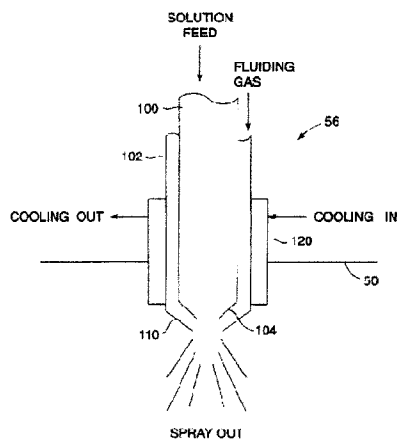


FIG. 3

Platz is directed to a different spray drying method than the present invention. Since each and every limitation of the pending claim is not inherently or expressly described, Platz does not anticipate amended claims 26, 28, 30 – 32, 40 – 45, 47 and 51 under 35 U.S.C. § 102(b).

Thus, in view of the foregoing amendments and arguments, Applicants respectfully request withdrawal of the rejection of claims 26, 28, 30 – 32, 40 – 45, 47 and 51.

### Rejection under 35 U.S.C. § 103(a)

Dependent claims 28, 35, 42, 43 and 47 were again rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Platz.

Initially, Applicants note that the Examiner has relied on a single reference as the basis for rejecting Applicants' claims under § 103(a). When a single reference is presented to support an obviousness rejection, the Examiner must cite evidence of general knowledge in the art that, together with the reference, makes a case for obviousness, or must submit – in the form of an

affidavit – Examiner’s own knowledge of facts that combine with the reference to make the claimed invention obvious. See 37 CFR § 1.104(d)(2); MPEP 2112(IV). The evidence must be “clear and particular.” *In re Dembiczak*. Importantly, since an Examiner is, under the law, not considered one skilled in the art, the Examiner’s opinion as to what one skilled in the art may (or may not) choose to do with the apparatus of Platz (e.g., derive a specific diameter of the fluid and/or gas channel constriction is of no moment. *In re Rijckaert* (“[T]he examiner’s assumptions do not constitute the disclosure of the prior art”). If the Examiner has knowledge of facts relevant to any of the pending rejections, the Examiner may file an affidavit to make those facts of record in the prosecution. The Examiner has submitted no such affidavit. Instead, the Examiner provides only an opinion and perfunctory/conclusory statements. The Examiner’s statements do not qualify as the requisite “evidence” needed to support an obviousness rejection. Therefore, Applicants respectfully request the pending rejection under 35 U.S.C. § 103 be withdrawn.

The Applicants respectfully submit that claims 28, 42, 43 and 47, as amended, are patentable since a *prima facie* case of obviousness has not been established. A *prima facie* case of obviousness must establish that the prior art reference or combination of references teach or suggest all the claimed limitations. M.P.E.P. § 2143. Each dependent claim incorporates each and every limitation of each claim from which it depends. Applicants hereby incorporate by reference its above arguments setting forth the differences between Platz and the present invention of amended independent claims 26 and 45.

By incorporating an atomizer comprising a first liquid flow channel wherein said first liquid flow channel comprises a constriction having a diameter less than 0.51 mm (0.020 in) for spreading a liquid into a thin film in the channel, the atomizer further comprising first and second gas flow channels for an atomizing gas flow, wherein said first liquid flow channel is intermediate to the first and second gas flow channels, said first and second gas flow channels being positioned so that the atomizing gas impinges the liquid thin film to produce droplets, the present invention of claims 28, 42, and 43 produce smaller and more uniform liquid droplet sizes than Platz. Additionally, the present invention of claim 47 comprising an atomizer comprising a first annular channel for a liquid flow, wherein said first annular channel comprises a constriction having a diameter less than 0.51 mm (0.020 in) for spreading a liquid into a thin film in the

channel, the atomizer further comprising a second annular channel for an atomizing gas flow, wherein said first and second annular channels are concentric, and said second annular channel is positioned in proximity to the first annular channel so that the atomizing gas impinges the liquid thin film to produce droplets, produces smaller and more uniform liquid droplet sizes than Platz.

The data in paragraph 0029 and Figure 5 of the published specification provides a direct comparison between the present invention over Platz:

The atomizer 40 according to the invention provides significantly improved atomization efficiency and allows for the ability to create smaller and more uniform liquid droplet sizes. For example, droplets less than 35 microns, and preferably less than 10 microns may be generated. The advantage of smaller droplet sizes is that a smaller final particle size for a given solid concentration may be obtained. Alternatively, a solid concentration may be increased while maintaining a particular particle size. This would allow for increased system throughput. The increased size distribution is shown in FIG. 5. FIG. 5 shows a graph of droplet diameter as a function of radial distance from the centerline of the atomizer for both the atomizer 40 of FIG. 4 and a prior art atomizer of U.S. Patent No. 6,051,256. As can be seen, the droplet diameter is significantly more uniform and smaller for the atomizer 40 of the present invention.

Platz and the present invention of claims 28, 42, 43 and 47, as amended, are directed to structurally and functionally different spray drying systems.

Moreover, as the independent claims are allowable over the prior art of record, then their dependent claims are allowable as a matter of law, because these dependent claims contain all features/elements/steps of their respective independent claim. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). Additionally and notwithstanding the foregoing reasons for the allowability of independent claim 26 or 45, the dependent claims recite further features/steps and/or combinations of features/steps (as is apparent by examination of the claims themselves) that are patentably distinct from the prior art of record. Hence, there are other reasons why these dependent claims are allowable.

Thus, in view of the foregoing amendments and arguments, Applicants respectfully request withdrawal of the rejection of claims 28, 42, 43 and 47 under 35 U.S.C. § 103(a).

Application. No. 10/738,912  
Reply to Office Action of December 17, 2009

Attorney Docket No.: PAT053285-US-CNT

**CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance, and the issuance of a formal Notice of Allowance is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650.283.6790.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Michael J. Mazza", written in black ink.

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Date: March 17, 2010